

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Wave 2 Cases Identified in
Exhibit A attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Anne Wilson, M.B.A.)

On July 21, 2016, the plaintiffs filed a Notice of Adoption of Prior *Daubert* Motion of Anne Wilson for Wave 2. [ECF No. 2421]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Anne Wilson) [ECF No. 2647] (“Prior Order”) entered on August 25, 2016, as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 2 cases identified in Exhibit A.¹ The Prior Order is attached hereto as Exhibit B.

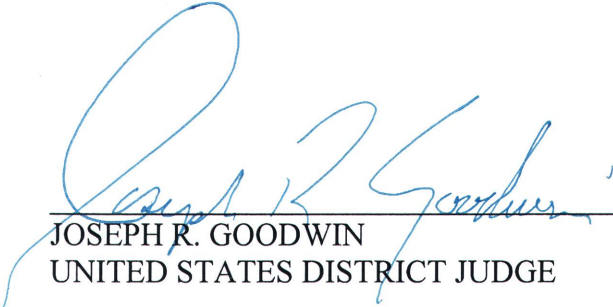
Importantly, the court notes that the expert opinions proffered in Wave 1 are in almost every respect identical to those proffered here. The court has found, however, that with each entered Order, the experts in these cases attempt to bolster or fine-tune the support for their opinions, but the opinions themselves do not change. Accordingly, the court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their

¹ On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 2, could not be identified because of an error in the style or case number, or assigned to another District Judge.

numerous opinions. While the parties continue to challenge even the slightest alteration to the underlying support for an expert's opinion, the court's review of the parties' arguments reveals that these refreshed *Daubert* challenges are different from previous arguments by only the very slightest of degrees. The court **FINDS** that to the extent that the parties raise arguments not previously addressed by the court's Prior Order, the trial judge may easily resolve these issues at trial without the need for further briefing or an evidentiary hearing. Accordingly, the court **ORDERS** that to the extent that the parties raise *Daubert* challenges not previously addressed in the court's Prior Order—fully adopted herein—those challenges are **RESERVED for trial**.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 2 cases identified in the Exhibit attached hereto.

ENTER: March 29, 2017



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

PLAINTIFF	CASE NUMBER	PRODUCT
Wilson, Tina	2:12cv02099	TVT
Swanson, Karen & Thomas	2:12cv01709	Gynemesh PS x2; TVT
Sutton, Martha	2:12cv01857	TVT Secur
Sierra, Ana & Luis	2:12cv01819	TVT Obturator
Shennum, Janice	2:12cv01708	TVT
Shelton, Mary & Frank	2:12cv01707	Prolene Mesh; TVT
Schroeder, Carreen & Matthew	2:12cv01327	TVT Obturator
Riggs, Donna & Gary	2:12cv01967	TVT
Raines, Myra & Kenneth	2:12cv01735	TVT
Pridmore, Hope Elaine & James O.	2:12cv02190	TVT Obturator
Pitts, Michelle	2:12cv02144	TVT
Pippin, Laura & Donald	2:12cv02152	TVT; TVT Obturator
Phillips, Ramona	2:12cv02143	TVT
Peterson, Tracy & Kevin	2:12cv02030	TVT
Parker, Belinda	2:12cv01710	TVT
Muir, Marilyn & Scott	2:12cv01706	TVT Obturator
Morrison, Laura R.	2:12cv02141	TVT Obturator
Miller, Rose M.	2:12cv02187	TVT Obturator
Meyer, Linda & Steve	2:12cv01705	Prolift Anterior; TVT
Messina, Laritza & John	2:12cv02140	TVT-O
McDonald, Maria Elena & Thomas	2:12cv01366	Gynemesh PS; TVT Obturator

Martin, Patricia J. & Dennis R., Sr.	2:12cv02185	TVT Obturator
Manor, Kristy & John E., III	2:12cv02137	TVT Obturator
Lewis, Marlene	2:12cv02139	TVT
Lambert, Corrie Ann & Ronson	2:12cv02183	TVT Obturator
Johnson, Cynthia & Robert	2:12cv01704	Prolift Total; TVT Obturator
Hoch, Susan & Christopher	2:12cv01703	TVT Obturator
Heuer, Myra	2:12cv01796	TVT
Guffey, Gail	2:12cv01650	TVT
Fleck, Jean E.	2:12cv01681	TVT
Fitzgerald, Alina DeeAnn & Christopher	2:12cv01371	TVT Obturator
Ferguson, Teresa	2:12cv01544	TVT Obturator
Crabtree, Reba & Jack	2:12cv02135	TVT
Colbert, Rhonda & Joseph	2:12cv01702	Gynemesh PS; TVT Obturator
Carroll, Margaret	2:12cv02026	TVT Obturator
Burnett, Mary K.	2:12cv01795	TVT Secur
Bihlmeyer, Donna & Joe	2:12cv02159	Prolift Total; TVT Obturator
Beard, Gavie & Kenneth	2:12cv02025	TVT Obturator
Bailey, Pamela & Houston	2:12cv01700	TVT
Anderson, Elaine	2:12cv02134	TVT

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Anne Wilson)

Pending before the court is the Motion to Exclude the Opinions and Testimony of Anne Wilson, M.B.A. [ECF No. 2083] filed by defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.¹

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

¹ Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2083-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by

precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Ms. Wilson is a biomedical engineer and quality assurance consultant with nearly thirty years of experience focusing on risk management, design controls, and quality system development for medical devices.

Because I have either excluded, reserved ruling on, or otherwise addressed the admissibility of Ms. Wilson's testimony on the grounds explained below in the Recurring Issues section, I find it unnecessary to address alternate challenges to her reliability or qualifications.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could

inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product’s risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this

type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert’s deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

Accordingly, the court **GRANTS in part** and **RESERVES in part** Ethicon's Motion to Exclude the Opinions and Testimony of Anne Wilson, M.B.A. [ECF No. 2083].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 25, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

EXHIBIT A WILSON

<u>Case Name</u>	<u>Case Number</u>	<u>Product</u>
Babcock, Marty	2:12cv01052	TVT
Barker, Daphne & Gary	2:12cv00899	TVT
Blake, Bonnie & Larry Miketey	2:12cv00995	TVT
Boggs, Sharon & Michael	2:12cv00368	TVT-O & Prolift
Byrd, Myra & Richard	2:12cv00748	TVT-O
Coleman, Angela & Timothy	2:12cv01267	TVT-O
Daino, Constance & Anthony	2:12cv01145	TVT
Destefano-Raston, Dina & Terry	2:12cv01299	TVT-O
Freitas, Monica & Kenneth	2:12cv01146	TVT
Gomez, Rose & Jesus	2:12cv00344	Prolift & TVT-O
Hankins, Dawna	2:12cv00369	TVT-O
Hankins, Donna & Roger	2:12cv01011	TVT
Hendrix, Mary & Thomas	2:12cv00595	TVT
Holzerland, Mary & Darin	2:12cv00875	TVT-S
Johnson, Myndal	2:12cv00498	TVT
Johnson, Wilma	2:11cv00809	Gynemesh PS & TVT
Jones, Holly & Jason	2:12cv00443	TVT
Kirkpatrick, Margaret	2:12cv00746	TVT-O
Kriz, Paula & James	2:12cv00938	Gynemesh PS & TVT-O
Lankston, Cheryl	2:12cv00755	TVT-S
Lozano, Deborah & Felipe	2:12cv00347	Prolift & TVT-O
Morrison, Angela & Bradley	2:12cv00800	TVT
Patterson, Miranda	2:12cv00481	TVT-O
Phelps, Patti Ann & James	2:12cv01171	TVT
Quijano, Maria Eugenia	2:12cv00799	TVT
Reyes, Jennifer & Jerry	2:12cv00939 (Duplicate Case: 2:15-cv-05664 - SFC filed on 05/05/2015 by Aylstock, Witkin Kreis & Overholtz	TVT
Sacchetti, Denise	2:12cv01148	TVT-O
Shultis, Stacy	2:12cv00654	TVT-O
Sikes, Jennifer	2:12cv00501	TVT-O
Smith, Carrie	2:12cv00258	TVT-O
Smith, Cindy	2:12cv01149	TVT
Teasley, Krystal	2:12cv00500	TVT-O
Thompson, Lisa & Roger	2:12cv01199	TVT-O

Warmack, Roberta & Thomas	2:12cv01150	TVT-O
Waynick, Laura & David	2:12cv01151	TVT